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In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 7991

Serial No.: 09/757,688

Examiner: L.S. Channavajjala

Filed: January 11, 2001

Group Art Unit: 1615

Title: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

TIMING AND FEES

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☒ a final rejection under 37 C.F.R. § 1.113;
 - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

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☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

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- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
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AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

STATEMENTS UNDER 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
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CITED MATERIALS

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.
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NON-ENGLISH LANGUAGE REFERENCES

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

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Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
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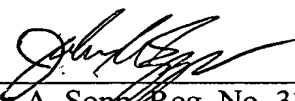
OTHER INFORMATION

None

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- ☐ Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: PLOVIN-2A

Date: December 10, 2003



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

Complete if Known

Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,569,652		Beier et al.	10-29-1996
	A4	5,583,129		Spona et al.	12-10-1996
	A5	5,824,667		Spona et al.	10-20-1998
	A6	5,827,843		Koninckx	10-27-1998
	A7	6,083,528		Elliesen et al.	07-04-2000
	A8	6,121,465		Mohr et al.	09-19-2000
	A9	6,346,269		Hsiao et al.	02-12-2002
	A10	RE37,564		Spona et al.	02-26-2002

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	DE	3022337	A1	Eiger et al.	01-07-1982		
	B2	UK	2192542	A1	Upton	01-20-1988		
	B3	WO	95/07081	A1	Koninckx	03-16-1995		
	B4	WO	95/17194	A1	Spona et al.	06-29-1995		
	B5	WO	95/26730	A1	Lachnit et al.	10-12-1995		
	B6	WO	97/01342	A1	Schmidt-Gollwitzer	01-16-1997		
	B7	WO	97/10827	A1	Petit et al.	03-27-1997		
	B8	WO	98/27929	A2	Nashed	07-02-1998		
	B9	WO	98/40069	A2	Klokckers et al.	09-17-1998		

NON PATENT LITERATURE DOCUMENTS

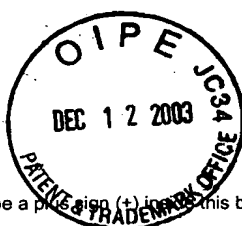
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	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	

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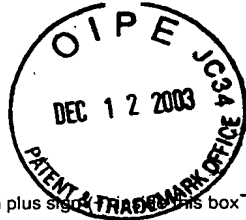
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		Examiner Name	L.S. Channavajjala
		Attorney Docket Number	PLOVIN-2A
Sheet	2	of	5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71	
	C3	Oelkers, "Effects of estrogens and progestogens on the renin-aldosterone system and blood pressure," <i>Steroids</i> , 1996 Apr.; 61(4): 166-71	
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	C5	Oelkers, "Effects of oral contraceptives on the renin - aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206	
	C6	Kincl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84	
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	C10	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951	
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	C16	Arias et al., "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," <i>Pharm-Acta-Helv.</i> , (71, No. 4, 229-35 1996)	
	C17	Shah et al., "Preformulation study of etoposide: identification of physicochemical characteristics responsible for the low and erratic oral bioavailability of etoposide," <i>Pharm. Res.</i> 1989 May; 6 (5):408-12	
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	C22	Bruzzese et al., "Action of Gastric and Intestinal Simulated Juice on Mepartricin Stability in Solid And Solubilized Form," <i>Il Farmaco - Ed. Pr.</i> , Vol. 32, No. 8, p. 422-428	
	C23	Andersson et al., "Pharmacokinetics and bioavailability of omeprazole after single and repeated oral administration in healthy subjects," <i>Br. J. clin. Pharmac.</i> , (1990), 29, 557-563	
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	C25	Nürnberg, "Manufacturing and Properties of Pharmaceutical Spray-Dried Products," <i>Acta Pharmaceutica Hungarica</i> 48. 19-35. 1978 (and English translation)	
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	C27	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432	
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	C29	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C30	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 5

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NON PATENT LITERATURE DOCUMENTS

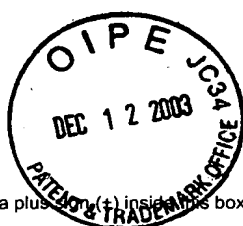
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C31	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256	
	C32	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38	
	C33	Fuhrmann et al., (1996) "The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential" <i>Contraception</i> , 54: 243-251	
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	C38	Wilson et al., (1984). "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C39	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
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	C44	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
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	C46	Hayward et al., "Effect of Combination Hormone Replacement Therapy on Ambulatory Blood Pressure and Arterial Stiffness in Diabetic Postmenopausal Women," <i>American Journal of Hypertension</i> , July 2001, Vol. 14, No. 7, Part 1, pp. 699-703	

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	C47	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
	C48	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194	
	C49	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655	
	C50	"Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," <i>JAMA</i> , January 18, 1995, Vol. 273, No. 3, 199-208	
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Examiner Signature	Date Considered
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